

**King, Valerie A.**

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**From:** Presting, Ortrun [Ortrun.Presting@parexel.com]  
**Sent:** Monday, August 05, 2002 12:48 PM  
**To:** 'Hans-Juergen.Roethig@pmusa.com'; Presting, Ortrun  
**Cc:** Jan.Oey@pmusa.com; Valerie.A.King@pmusa.com  
**Subject:** RE: EHCJLI/03/02-ACCORD Menthol

**Sensitivity:** Confidential



PhilipMorrisICF080502.

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Dear Hans,

Attached please find the revised ICF. Also, please fax me a signed protocol signature page for submission purposes tomorrow. Valerie, can you please send me the original overnight? We will need something for submission tomorrow.

Thank you,

Ortrun

-----Original Message-----

**From:** Hans-Juergen.Roethig@pmusa.com  
**[ <<mailto:Hans-Juergen.Roethig@pmusa.com>> ]**  
**Sent:** Monday, August 05, 2002 12:41 PM  
**To:** Ortrun.Presting@parexel.com  
**Cc:** Jan.Oey@pmusa.com; Valerie.A.King@pmusa.com  
**Subject:** FW: EHCJLI/03/02-ACCORD Menthol  
**Sensitivity:** Confidential

Dear Ortrun,  
here is the revised protocol for the ACCORD JLI Menthol study. Please use also the comments Jan sent you for revising the Informed Consent. Please send us a copy of the IC, once you revised it.

Best regards

Hans J Roethig, MD, PhD, FCP, FFPM  
Director Clinical Evaluation  
Philip Morris USA  
615 Maury Street  
Richmond, VA 23224  
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e-mail: hans-juergen.roethig@PMUSA.com

-----Original Message-----

**From:** Michael Szwaneck (402)437-4880 [ <<mailto:Michael.Szwaneck@mdsps.com>> ]  
**Sent:** Monday, August 05, 2002 12:40 PM  
**To:** Hans-Juergen.Roethig@pmusa.com

Cc: jan.oey@pmusa.com; Kimberly Prchal; Robert Earl; Kirk Newland  
Subject: EHCJLI/03/02-ACCORD Menthol  
Sensitivity: Confidential

Hans,

Attached is the protocol and Selected Attachments dated August 5, 2002 for EHCJLI/03/02-ACCORD Menthol study to be conducted by PAREXEL. I have incorporated all of Amendment One changes into this version of the protocol so Amendment One is no longer valid or required. In addition I revised the IRB to Chesapeake Research Review, Inc. Another additional change was made for urine collection for 3-HPMA and NNAL and NNAL-glucuronide. We will now collect these samples in HDPE as it has been determine that silanized glass is no longer required.

Thanks,

Michael F. Szwaneck, Pharm D., MBA  
Senior Scientist, Study Design & Protocol Development  
MDS Pharma Services - Lincoln, NE  
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(402) 437-4880